Clarifying Oral Public Comment on the
CASAC Review of EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)

The Clean Air Act, Not CASAC, Defines the Decision Context of the National Ambient Air Quality Standards

ORAL COMMENT BY:
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Washington, DC

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This is an oral statement made to the Clean Air Scientific Advisory Committee during the period for clarifying public comments at its October 24, 2019 meeting regarding the review of EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019).

Thank you Mr. Aaron Yeow. Thank you, members of the CASAC. I'm going to try to be quick and cover a lot of things.[2]

When we met as the Independent Particulate Matter Review Panel (IPMRP) a couple of weeks ago, we had 20 experts engaged.[3] We had 16 assigned discussants under Charge Question 3

[1] A biosketch is given on the last page.

[2] Speakers delivering clarifying public comments were limited to 3 minutes.

[3] Frey, H.C., P. Adams, J.L. Adgate, G. Allen, J. Balmes, K. Boyle, J.C. Chow, D.W. Dockery, H. Felton, T. Gordon, J.R. Harkema, J. Kaufman, P. Kinney, M. Kleinman, R. McConnell, R.L. Poirot, J.A. Sarnat, E.A. Sheppard, B. Turpin, and R. Wyzga, "Advice from the Independent Particulate Matter Review Panel (formerly EPA CASAC Particulate Matter Review Panel) on EPA's Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft – September 2019)," 11 page letter and 192 pages of attachments submitted to Hon. Andrew Wheeler, Administrator, Docket ID No. EPA–HQ–OAR–2015–0072, and Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Washington, DC, October 22, 2019

(regarding the primary $PM_{2.5}$ standards).[4] You had two plus the chair. As the chair of the IPMRP, I didn't assign myself to charge questions. I don't think that's an appropriate role of the chair.[5]

Regarding the lack of epidemiologic expertise on this CASAC: there are certainly questions that can be *asked* about confounding. However, you can't *answer* those questions because you don't have the needed expertise and the domain knowledge at this table. I want to read you a quote from the IPMRP report of October 22, 2019: "In studies of long-term exposure to particulate matter, there is neither rationale nor empirical support for concern over confounding by temperature."[6,7] We find that the annual studies provide evidence of the bulk of premature mortality from fine particle exposure.[8]

You are also ignoring at risk populations in your deliberations.[9]

I'm convinced that this CASAC does not understand the statutory mandate of the Clean Air Act for the decision context.[10] The decision context is not for Tony Cox to define. It's not for any of you to define. It's given to you by Congress. In December 2018, during clarifying public oral comments, I recommended that you ask the EPA Office of General Counsel to explain to you

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https://yosemite.epa.gov/sab/sabproduct.nsf/81DF85B5460CC14F8525849B0043144B/$File/Independent+Particulate+Matter+Review+Panel+Letter+on+Draft+PA.pdf

[4] Please see the agenda of the October 10-11, 2019 meeting of the Independent Particulate Matter Review Panel, which is available at: https://ucs-documents.s3.amazonaws.com/science-and-democracy/pm-panel-meeting-docs/ipmrp-agenda.pdf

[5] In my opening remarks as Chair of the Independent Particulate Matter Review Panel, I stated "My goal as chair is to make sure you, the experts, have the opportunity to provide your input." See a video of the first day of our Oct 10-11, 2019 meeting. https://www.youtube.com/watch?v=wpodC23hJnQ&feature=youtu.be. My statement on this matter occurs at 28 minutes, 30 seconds of the video recording.

[6] As someone who observed the CASAC meeting on October 24 and 25, 2019, other than a statement from Dr. Frampton to the effect that daily temperature cannot be a confounder for epidemiologic studies based on annual exposures, I did not hear other members of the CASAC acknowledge this point. I also did not hear other members of CASAC acknowledge that there is a much larger share of observed and estimated premature mortality from annual vs. daily exposures to fine particles. These points should be acknowledged in CASAC's draft letter on the draft Policy Assessment.

[7] The Independent Particulate Matter Review Panel roster includes multiple epidemiologists. See the roster and biographical sketches that are part of the Panel's report (see footnote 2).

[8] In a subsequent clarifying public comment, delivered after I spoke, Dr. Dan Greenbaum of the Health Effects Institute stated that indicators of daily temperature have been taken into account in epidemiologic studies of daily exposures to fine particulate matter.

[9] Members of CASAC should carefully read Chapter 1 of the draft Policy Assessment, including the interpretation based on case law that the national ambient air quality standards must be protective of not just the general population but also subgroups of the population. Over time, the framing of these subgroups has evolved into what are now described as "at risk" populations.

[10] My statement here is based on direct personal observations of CASAC face-to-face and teleconference meetings during this review cycle for particulate matter dating to December 12-13, 2018. In the December 2018 meeting, at least one CASAC member did not understand why there was a chapter on at risk populations in the draft ISA. During the October 24-25, 2019 meeting, the chair framed the decision context in terms of his own framework and that of another member of CASAC. I did not hear the chair make any reference to Sections 108 and 109 of the Clean Air Act. I did not hear the chair acknowledge points made in Chapter 1 of the draft Policy Assessment regarding the decision context set forth not just in the Clean Air Act but also as a result of case law based on decisions of Federal courts. The CASAC defined its own decision context and framework irrespective of that intended by Congress as interpreted by Federal courts.

what that decision context is.[11] I have yet to see that happen. When I chaired CASAC and CASAC review panels, I asked for this. Why don't you?

You need to bring a panel to the table. You need the expertise at the table. Having a pool that you can't even deliberate with, that's not appointed specific to PM, is not solving that problem.

I don't know why the Administrator is playing these games with you, but it is not helping you and it is not helping the Agency.

Dr. Cox has used the phrase "sound science." That is often an ideological statement to require a higher burden of proof than is required by the statute.[12,13] Based on his remarks, that's exactly where he's going with this.[14] That's why I emphasize that you need to understand the law.

This panel is making judgments. You are not conditioned to make these judgments. A key predicate of expert judgment formation is conditioning based on the full body of evidence.[15] You

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[11] Frey, H.C. "Clarifying Oral Comment," to the Clean Air Scientific Advisory Committee, U.S. Environmental Protection Agency, Crystal City, VA, December 13, 2019. https://yosemite.epa.gov/sab/sabproduct.nsf/0471352D965DF693852583620007AEA3/$File/List+of+speakers-121218-clarifying+comments.pdf

See also an article published December 14, 2018 by InsideEPA, "Former CASAC Chairman Warns 'Joke' Review Hurts PM NAAQS Assessment"

[12] An example of a discussion of the meaning of "sound science" in the context of environmental regulation is given by Ruden and Hansson (2008) in "Evidence-Based Toxicology: "Sound Science" in New Disguise," *International Journal of Occupational and Environmental Health*, October 2008, 299-306.

[13] Section 109 of the Clean Air Act states "National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." The phrase "such criteria" refers to Section 108 of the Clean Air Act, which specifies that "[a]ir quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on--(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant; (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and (C) any known or anticipated adverse effects on welfare." The language of Sections 108 and 109 have been interpreted by Federal courts, including the U.S. Supreme Court. This language is understood to allow for protection of public health even when there are uncertainties, and to allow for protection of at risk populations in addition to the general population. Protection does not, however, require zero risk. The level of protection required under the Clean Air Act does not require scientific certainty as a basis for setting a standard.

[14] On October 25, 2019, shortly after the CASAC meeting reconvened for a second day, Dr. Cox referenced and partially responded to my remark above regarding "sound science". In his remarks, Dr. Cox did not address the key point in my comment that members of this CASAC are imposing a burden of proof beyond that required by the statute. In addressing my comment about "sound science" in his opening remarks on Oct 25, Dr. Cox: (1) did not state that he would ask the EPA Office of General Counsel for an explanation of the decision context of the NAAQS review; (2) did not ask any of the other members of CASAC if they would like to hear from the EPA Office of General Counsel regarding the decision context for the NAAQS review; (3) did not acknowledge my advice to ask the EPA Office of General Counsel for an explanation of the decision context of the NAAQS review; (4) did not explain why CASAC has not asked for such an explanation nor provide any rationale for why CASAC will not seek such input; and (5) did not summarize his or the CASAC's understanding of the decision context as set forth in Sections 108 and 109 of the Clean Air Act and as interpreted by Federal courts. Especially at this stage of NAAQS review, during which CASAC is deliberating on a draft Policy Assessment, it has been common, in my experience (having served on 10 CASAC review panels and chaired three of them), to provide a few minutes for the EPA Office of General Counsel to share their perspective on these matters and answer clarifying questions from members of the cognizant CASAC review panel.

[15] I provide explanation of the concept of "conditioning" in my individual written comments that are part of the report from the Independent Particulate Matter Review Panel (see footnote 2).

don't even have the right disciplines represented at the table. It's not good enough to say "well, we can do what we can do." The review of criteria for the standard needs to be thorough, not partial, not based on just what you have here at the table.[16]

There's lots more that can be said, but we've largely said it in our Panel report. I hope you will please read that. We certainly wish you well and are available to help. Thank you.

[16] Section 109 of the Clean Air Act states that "the Administrator shall complete a thorough review of the criteria" published under Section 108. The "criteria" refer to the scientific basis for the review. In the past, the criteria were established in a "criteria document". Since about 2007, the criteria have been established in the "Integrated Science Assessment". The independent committee now known as the Clean Air Scientific Advisory Committee is required, under Section 109 of the Clean Air Act, to "complete a review of the criteria." CASAC is not able to do this if it lacks the needed expertise. In particular, but not exclusively in this case, the CASAC lacks expertise in epidemiology and is, therefore, unqualified to complete a review of the epidemiological evidence that is a key component of the criteria for the primary PM standards. While this is not the fault of any individual member of the CASAC, it is the fault of the EPA Administrator, who arbitrarily and capriciously disbanded the CASAC PM Review Panel just days before the draft ISA (which is the basis for the criteria) was issued. The CASAC PM Review Panel was qualified, competent, and capable to review the draft ISA and to augment the CASAC for that purpose consistent with CASAC's charter with the U.S. Congress. Likewise, the CASAC PM Review Panel appropriately would have provided CASAC with the expertise needed to review the draft Policy Assessment.

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Biosketch

Dr. H. Christopher Frey is the Glenn E. Futrell Distinguished University Professor of Environmental Engineering in the Department of Civil, Construction, and Environmental Engineering at North Carolina State University. Dr. Frey's research includes quantification of uncertainty in engineering process technologies and emission factors, probabilistic methods for exposure assessment, measurement and modeling of human exposure to air pollution, and measurement and modeling of vehicle emissions. He teaches courses on air pollution control, environmental exposure and risk assessment, and sustainable infrastructure. Dr. Frey is an adjunct professor in the Division of the Environment and Sustainability at the Hong Kong University of Science and Technology, where he has taught a course on urban air quality and is part of a large team developing an exposure model for Hong Kong.

Dr. Frey served as a member (2008-2012) and chair (2012-2015) of the U.S. Environmental Protection Agency's Clean Air Scientific Advisory Committee (CASAC), has chaired CASAC Review Panels on Lead, Nitrogen Dioxide, and Ozone, and has served on CASAC Review Panels for all criteria pollutants include Lead, Nitrogen Dioxide, Ozone, Carbon Monoxide, Particulate Matter, and Sulfur Oxides. He served on the U.S. EPA Science Advisory Board from 2012 to 2018. For the National Greenhouse Gas Inventory Program of the Intergovernmental Panel on Climate Change (IPCC), he served as an expert and Lead Author for the chapter on uncertainties for the 2006 IPCC Guidelines on National Greenhouse Gas Emission Inventories, and in 2016 was an invited expert regarding updates to the 2006 Guidelines. Additionally, he was a technical contributor to the U.S. Department of Transportation's 2010 Report to Congress regarding Transportation's Role in Reducing U.S. Greenhouse Gas Emissions. He served on a World Health Organization working group that developed guidance on uncertainty in exposure assessment (2006). He served on two National Research Council (NRC) committees and was a member (2009-2012) of the NRC Board of Environmental Studies and Toxicology. He currently serves on the MOVES Model Review Work Group of the Mobile Sources Technical Review Subcommittee of the EPA Clean Air Act Advisory Committee (CAAAC).

In the last two years, Dr. Frey has been the principle investigator of research grants and research contracts at North Carolina Statement University sponsored by the North Carolina Department of Transportation, the U.S. Environmental Protection Agency via the Health Effects Institute and Eastern Research Group, and the Urban Air Initiative. Dr. Frey's research work at HKUST is funded by the HSBC 150th Anniversary Charity Programme. Dr. Frey has also conducted work for the Hong Kong Environmental Protection Department. Dr. Frey's current affiliations include serving as a member of the Transportation and Air Quality (ADC20) Committee of the Transportation Research Board, and as a member of the Publications Committee and the Critical Review Committee of the Air & Waste Management Association (A&WMA)

Dr. Frey is a Fellow of the Air & Waste Management Association (A&WMA) and of the Society for Risk Analysis (SRA), served on the A&WMA Board of Directors (2015-2018), and was President of SRA in 2006. He received the Chauncey Starr Award from SRA in 1999, the Lyman A. Ripperton Award from A&WMA in 2012, and the Frank A. Chambers Award from A&WMA in 2019. He has a B.S. in mechanical engineering from the University of Virginia, a master of engineering in mechanical engineering from Carnegie Mellon University, and Ph.D. in engineering and public policy from Carnegie Mellon.